AF

PATENT
Customer No. 22,852
Attorney Docket No. **2481.1726-00**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Petra LOOS et al.	)	Group Art Unit: 1743
	)	
Application No.: 09/763,733	)	Examiner: S. Siefke
	)	
Filed: February 27, 2001	)	
	)	
For: MINI-BASKET FOR ANALYZING ACTIVE SUBSTANCE RELEASE FROM A MEDICAMENT FORM	)	

Mail Stop Appeal Brief--Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

NOTICE OF APPEAL

Applicants hereby appeal to the Board of Appeals from the final decision of the Examiner dated October 22, 2003.

A Petition for Extension of Time - Three Months to extend the period for response to April 22, 2004 is enclosed together with a fee of $950.00.

The Appeal Fee of $330.00 is enclosed.

A check for $1,280.00 to cover the above fees is enclosed.

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Please grant any extensions of time required to enter this Notice of Appeal and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: April 21, 2004

By: _____
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Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

Appellant's Appeal Brief in connection with the above-captioned patent application is hereby submitted in triplicate. A Notice of Appeal was timely filed on April 21, 2004, in response to the final Office Action of October 22, 2003. Each item required by 37 C.F.R. § 1.192 is set forth below.

Pursuant to 37 C.F.R. § 1.192(a), the fee payment of $330.00 is enclosed with this Appeal Brief.

I. Real Party In Interest

The real party in interest is Aventis Pharma Deutschland GmbH, located at Brüningstrasse 50, D-65929 Frankfurt am Main, Germany.

II. Related Appeals and Interferences

On information and belief, there are no related Appeals or Interferences.

III. Status Of Claims

Claims 1-7 have been canceled. Claims 8-31 are currently pending in this application. Claims 25-31 have been withdrawn from consideration as drawn to a non-elected invention. Claims 8-24 are the subject of this appeal. A clean copy of claims 8-24 is found in the Appendix.

IV. Status Of Amendments

No Amendments After Final have been filed in this application.

V. Summary Of Invention

The present invention, as defined by independent claim 8, is directed to a device configured to fit within an in vitro substance release testing apparatus. The in vitro substance release testing apparatus is at least one of a paddle agitator, a continuous flow cell, and a rotating basket apparatus. The device is a mini-basket that includes a mesh basket configured to receive a material to be tested and configured to fit within the in vitro substance release testing apparatus. The mini-basket also includes a lid having a handle on one side of the lid. The handle is configured to permit movement of the mini-basket between one testing apparatus and another testing apparatus. The basket is not physically connected to the testing apparatus, and therefore can easily be moved between apparatuses by the handle on the lid.

VI. Issues

There are two issues on appeal, as set forth below:

(1) Whether claims 8-17, 19, and 21-24 recite patentable subject matter under 35 U.S.C. § 102(b) based on Mehta et al., U.S. Patent No. 4,856,909.

(2) Whether claims 18 and 20 recite patentable subject matter under 35 U.S.C. § 103(a) based on Mehta et al.

VII. Grouping Of Claims

Claims 8-24 stand or fall together.

VIII. Argument

The final rejections should be reversed for the reasons set forth herein.

A. First Issue: Rejection Under 35 U.S.C. § 102(b)

Claims 8-17, 19, and 21-24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mehta et al. Pages 3-4 of the Final Rejection.

1. Law on Anticipation Under 35 U.S.C. § 102(b):

35 U.S.C. § 102(b) states:

> A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than a year prior to the date of application for patent in the United States.

Accordingly, a person is not entitled to a patent if the claimed invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than a year prior to the filing date of the U.S. patent application. Claims of a patent application not entitled to a patent under the conditions of 35 U.S.C. § 102(b) are rejected by a Patent Examiner as anticipated by the cited prior art patent or printed publication. A claim is anticipated, however, only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053, (Fed. Cir. 1987). Further, an anticipating prior art patent or printed publication must describe the patented subject matter with sufficient clarity and

detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); Diversitech Corp. v. Century Steps, Inc., 850 F.2d 1566, 1567, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988).

2. Mehta et al. Does Not Disclose a Handle

The rejection of claims 8-17, 19, and 21-24 under 35 U.S.C. § 102(b) should be withdrawn because Mehta et al. does not disclose, either expressly or inherently, each and every element set forth in the claims. For example, claim 8 requires that at least the following feature of the claimed device be present:

a lid including a handle on one side of the lid, the handle being configured to permit movement of the mesh basket between one testing apparatus and another testing apparatus.

In rejecting claims 8-17, 19, and 21-24, the Examiner asserted that Mehta et al. discloses the invention as claimed. More specifically, the Examiner asserted that Mehta et al. discloses a pharmacological dissolution apparatus comprising a mesh basket configured to receive a material to be tested and a lid including a handle on one side of the lad opposite the handle. Final Rejection, page 3.

In response to Applicants' arguments that Mehta et al. does not disclose a handle, the Examiner asserted that the drive shaft 12 of Mehta et al. may be considered a handle because the drive shaft 12 may be used to carry the connected mesh basket. The Examiner relied upon a definition of a handle found in Webster's Dictionary, which allegedly states that a handle is "a part that is designed especially to be grasped by the hand" (emphasis added). The Examiner asserted that the cylindrical shape of the drive

shaft enables it to be grasped by a hand, and therefore the drive shaft is structurally capable of performing the function of a handle. Final Rejection, page 2.

Applicants disagree with the Examiner's assertion. Mehta et al. does not disclose or suggest the use of a structure especially designed to be grasped by the hand to allow the user to carry the basket or remove the cover of the basket. The drive shaft 12 disclosed in Mehta et al. is not a handle. Contrary to the Examiner's assertion, the drive shaft is not "designed especially" to be grasped by the hand. Rather, it is designed to rotate relative to inner shaft 14 and rotate the basket 18. As set forth in col. 5, lines 19-22, inner vertical shaft 14 and outer shaft 12 are controllably rotatable one with respect to the other by a conventional drive system 63. Further, as discussed in col. 5, lines 26-31, the central shaft is held fixedly and the hollow outer shaft 12 is rotated. Specifically, Mehta et al. teaches that "in the preferred embodiment shown in the drawings, inner shaft 14 is held fixed to a support while the outer shaft 12 is rotated." Col. 5, lines 29-31. Since the outer shaft 12 is rotating during use, it follows that it is not "designed especially" to be grasped by the hand as it would rotate in the holder's grasp, and therefore, it cannot be grasped by a hand. In addition, even assuming *arguendo* that the outer shaft 12 could be grasped when the outer shaft 12 is not rotating, as shown in Figs. 1 and 2 of Mehta et al., at least a portion of drive shaft 12 is inaccessible as it is positioned below the testing medium or solvent 20 of the testing apparatus. Depending on the length of outer shaft 12, in order to have sufficient leverage to manuever shaft 12 and basket 18 out of container 10, it would be expected for a person to grasp the outer shaft 12 near basket 18 to remove it. Applicants assert that even in its non-rotating state, shaft 12 cannot function as a handle because it would

require a person to insert his hand into the solvent 20, often an acid, in order to grasp the shaft 12 to remove the basket from the solvent.

Even assuming *arguendo* that the drive shaft 12 was able to be grasped by hand, whether rotating or not, there is no motivation for one of ordinary skill in the art to use the drive shaft 12 as a handle, as to do so could likely impair the proper operation of the drive shaft 12. For example, oils and other dirt from the hand could impede proper rotation of the drive shaft 12. In addition, holding the drive shaft 12 as it rotates could alter the rate of rotation thereby affecting the dissolution rate of the material being tested. Further, using the drive shaft 12 as a handle, even when the drive shaft is not rotating, could cause stresses on shaft 12 itself and on other parts of the basket 18 and chuck 40 that those parts are not designed to withstand, thus potentially causing permanent damage to the device and/or a person attempting to grasp the drive shaft 12. Indeed, Mehta et al. discloses that one of its attendant advantages is a reduction in mechanical vibrations, something that would not occur were the drive shaft 12 used as a handle.

3. Mehta et al. Does Not Disclose a Handle on the Lid

Independent claim 8 of the present application recites a combination including "a mesh basket configured to receive a material to be tested and configured to fit within the in vitro substance release testing apparatus; and a lid including a handle on one side of the lid, the handle being configured to permit movement of the mesh basket between one testing apparatus and another testing apparatus." The present invention is intended to be used in various types of testing apparatuses, and to be moved between apparatuses containing different solvents. The handle on the lid of the basket facilitates removal of the basket from one apparatus and insertion into a different apparatus.

Mehta et al. does not disclose removing the basket 18 from one apparatus and inserting the basket 18 into a different apparatus.

A handle is defined on page 616 of The American Heritage College Dictionary, (3rd ed., 1993), as "[a] part that is designed to be held or operated with the hand." As stated previously and shown in Figs. 2 and 4, Mehta et al. does not disclose or suggest a part that is designed to be held or operated with the hand. Instead, Mehta et al. discloses a chuck 40 used to close the container and including three spring clips extending around the lid to engage with slots 32 of end ring 26. Chuck 40 is formed around and connected to horizontal drive shaft 16 via bearing 62 and bevel gear 52. Horizontal drive shaft 16 is in turn connected to inner drive shaft 14 and outer drive shaft 12 via bevel gear 50 and a couple of bearings 60. Indeed, outer drive shaft 12 and chuck 40 do not even physically come into contact with each other, as Fig. 2 discloses a gap between outer drive shaft 12 and chuck 40. Thus, contrary to the Examiner's assertion on page 2 of the final rejection, the drive shaft 12 is not structurally attached to the top of the lid. Mehta et al. is completely silent as to the use of a handle on the lid of its apparatus, and the figures do not disclose or suggest the use of a handle.

Further, there is no motivation for one of ordinary skill in the art to provide Mehta et al. with a handle on its lid. A handle would interfere with the operation of the horizontal drive shaft 16 and outer drive shaft 12, thus rendering Mehta et al.'s apparatus inoperable. Further, a handle on the lid of the basket of Mehta et al. would be inoperable because it could not be reached without a user placing his hand into the testing medium (solvent). Thus, Mehta et al. cannot anticipate or render obvious the invention recited in claim 8.

4. **M hta et al. Does Not Disclos a Paddl Agitator or a Continuous Flow Cell**

The Examiner is incorrect in his assertion that Mehta et al. discloses each of a paddle agitator and a continuous flow cell. On page 2 of the Final Rejection, the Examiner asserts that col. 4, lines 55-61 of Mehta et al. disclose a paddle agitator. However, col. 4, lines 55-61, simply disclose providing fins or blades on the exterior of the basket, which is not a paddle agitator as recognized by one of ordinary skill in the art. On pages 2-3 of the Final Rejection, the Examiner asserts that col. 3, line 66 through col. 4, line 2 discloses a continuous flow cell. However, col. 43, line 66 through col. 4, line 2 disclose flowing a solvent substantially over all of the exterior surfaces of a dosage unit, which is not a continuous flow cell as recognized by one of ordinary skill in the art. Indeed, Applicants submit that the background section of Mehta et al. talks about prior art devices generally, and in no way suggests or discloses that the basket of Mehta et al. be used with a paddle agitator or continuous flow cell. Mehta et al. discloses a rotating basket apparatus that would not fit within a paddle agitator or continuous flow cell apparatus. Chuck 40 closes the container and includes three spring clips 30 extending around the chuck 40 to engage with slots 32 of end ring 26. Chuck 40 is formed around and connected to horizontal drive shaft 16 via bearing 62 and bevel gear 52. Horizontal drive shaft 16 is in turn connected to inner drive shaft 14 and outer drive shaft 12 via bevel gear 50 and a couple of bearings 60. Drive shaft 12 is connected to a drive system 63. The basket 18 and chuck 40 of Mehta et al. are an integral portion of the testing apparatus of Mehta et al. Unlike the present invention, the basket 18 and chuck 40 of Mehta et al. are not configured or intended to be used with

different types of testing apparatus. Mehta et al. does not disclose or suggest use of its device with a paddle agitator or a continuous flow cell.

Favorable consideration of claims 8-17, 19, and 21-24 and reversal of this rejection is respectfully requested.

B. Second Issue: Rejection Under 35 U.S.C. § 103(a)

Claims 18 and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mehta et al. Pages 3-4 of the Final Rejection.

The rejection of claims 18 and 20 under 35 U.S.C. § 103(a) as obvious over Mehta et al. should be reversed because the Examiner has failed to support a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, three basic criteria must be satisfied. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine references. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim elements. See MPEP § 2143.

MPEP § 2143.01 discusses the requirement of establishing a suggestion or motivation to combine references in a *prima facie* case of obviousness. For instance, as stated in § 2143.01, "the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *Id., citing In re Mills*, 926 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). In order to establish a *prima facie* case of obviousness, the prior art references must teach or suggest all of the claimed limitations. The teaching or

suggestion to make the claimed combination must be found in the prior art, and not in applicant's disclosure. See M.P.E.P. § 2142; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As set forth above, Mehta et al. does not disclose or suggest at least the following feature of the claimed device:

a lid including a handle on one side of the lid, the handle being configured to permit movement of the mesh basket between one testing apparatus and another testing apparatus.

Accordingly, the third basic criteria for establishing a *prima facie* case of obviousness has not been met.

Moreover, the Examiner admits on page 5 of the Final Rejection that "Mehta does not teach the lid of the basket be made of mesh." However, the Examiner then asserts that "[i]t would have been obvious to one of ordinary skill in the art to modify Mehta to have a lid that is mesh in order to maximize fluid flowing through the basket."

Applicants disagree with the Examiner's assertion. One of ordinary skill in the art would not be motivated to have a lid that is mesh. As shown in Fig. 2, the chuck 40, asserted by the Examiner as corresponding to the lid, is comprised of a solid material with a considerable thickness so as to support the connection between the basket 18 and drive shafts 12, 14. Such a configuration of the chuck 40 is necessary because the chuck 40 must be structurally strong enough to support several functions which would be impeded by such a configuration.

For example, the chuck 40 facilitates the securing of the basket 18 to the horizontal drive shaft 16 via three spring clips 30 cooperating with the slots 32 on the ring 26. Introducing mesh into the chuck 40 could compromise its structural integrity

and allow bending of the chuck 40 relative to the horizontal shaft 16 that would reduce the secureness of the connection between the three springs clips 30 and the slots 32 on the ring 26. Without a secure connection between the three springs clips 30 and the slots 32 on the ring 26, the basket 18 would fly off during the horizontal rotation of the basket 18 about the horizontal drive shaft 16, impeding the dissolution of the pharmacological dosage unit disposed in the basket 18, and thus impermissibly render the prior art invention unsatisfactory for its intended use. *In re Gordon*, 733 F.2d 900, 22 USPQ 1125 (Fed. Cir. 1984).

In another example, the chuck 40 facilitates the rotating of the basket 18 about the horizontal drive shaft 16. The chuck 40 is connected to the horizontal shaft 16 via a pin 56. The horizontal shaft 16 rotates within bearings 60, 62 and is driven by inner drive shaft 14 via bevel gears 50, 52. Introducing mesh into the chuck 40 could compromise its structural integrity, and allow bending of the chuck 40 and the horizontal shaft 16 relative to other components. Such bending would prevent the horizontal shaft 16 from properly rotating within bearings 60, 62, and prevent the bevel gears 50, 52 from properly engaging so as to allow the inner drive shaft 14 to rotate the horizontal shaft 16. If the horizontal shaft 16 did not properly rotate, the principle of operation of the prior art invention would be impermissibly modified, *In re Ratti*, 270 F.2d 810, 123, USPQ 349 (CCPA 1959), and the prior art invention would impermissibly be rendered unsatisfactory for its intended use. *In re Gordon*, 733 F.2d 900, 22 USPQ 1125 (Fed. Cir. 1984).

Favorable consideration of claims 18 and 20 and reversal of this rejection is respectfully requested.

Conclusion

In conclusion, Appellant submits that the rejections of claims 8-24 should be reversed. Mehta et al. does not disclose or suggest the use of a handle on a lid of its basket. Further, there is no motivation to provide a handle for the rotating basket of Mehta et al. because such a handle would be inoperable. Therefore, Mehta et al. cannot anticipate or render obvious claim 8 or any claim that depends therefrom.

To the extent any further extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
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Dated: April 21, 2004

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Appendix of the Claims Appealed

8. A device configured to fit within an in vitro substance release testing apparatus, the in vitro substance release testing apparatus being at least one of a paddle agitator, a continuous flow cell, and a rotating basket apparatus, the device comprising:

a mesh basket configured to receive a material to be tested and configured to fit within the in vitro substance release testing apparatus; and

a lid including a handle on one side of the lid, the handle being configured to permit movement of the mesh basket between one testing apparatus and another testing apparatus.

9. The device of claim 8, wherein the lid includes at least one fixing clip on a side of the lid opposite the handle.

10. The device of claim 8, wherein the basket is cylindrical in shape and includes an open end and a closed end.

11. The device of claim 10, wherein the basket includes a narrow metal band around at least an open end of the basket.

12. The device of claim 8, wherein the handle includes a bracket configured to allow removal of the device from the testing apparatus.

13. The device of claim 8, wherein the device is configured to fit within a paddle agitator.

14. The device of claim 8, wherein the device is configured to fit within a continuous flow cell.

15. The device of claim 8, wherein the device is configured to fit within a rotating basket apparatus.

16. The device of claim 8, wherein the device is configured to fit within a paddle agitator and a continuous flow cell.

17. The device of claim 8, wherein the material to be tested is a medicament in solid form.

18. The device of claim 8, wherein the lid is formed of a mesh material.

19. The device of claim 8, wherein the lid is a plate.

20. The device of claim 18, wherein the handle is attached to the lid in a manner which maximizes the amount of the lid surface through which a fluid may pass.

21. The device of claim 9, wherein the fixing clip is configured to connect the lid to the basket.

22. The device of claim 9, wherein the lid includes three fixing clips.

23. The device of claim 19, wherein the handle includes a rod.

24. The device of claim 8, wherein the mesh forming the basket is a wire screen fabric.